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EXAMINER

DECLoux, AMY M

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 03/11/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N .

09/855,612

Applicant(s)

SPIES ET AL.

Examiner

Amy M. DeCloux

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-101 is/are pending in the application.
- 4a) Of the above claim(s) 26-101 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1644

### DETAILED ACTION

It is noted that the instant claims contain claims numbered 1-72, 74-100 and 102-103. According to Rule 1.126, claims 74-100 have been renumbered as claims 73-99, and claims 102-103 have been renumbered 100-101. Applicant is required to make any necessary changes in claim dependencies.

#### *Election/Restrictions*

1. Applicant's election without traverse of Group 1, claims 1-25, in Paper No. 8, filed 1-7-03, is acknowledged.
2. Claims 26-101 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8, filed 1-7-03.
3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### *Priority*

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. See MPEP 1302.04.

Specifically, it is noted that the first line of the specification refers only to provisional application 60/029,044. Reference must be made to parent applications 09/303,161 and PCT/US97/20170.

**The following paragraphs** clarifies how benefit claims under 35 U.S.C. §§ 119((e), 120, 121 and 365(c) must be presented in applications in order to be in compliance with the relevant statute and patent regulations, and accepted by the United States Patent and Trademark Office (Office).

#### **35 U.S.C. § 120 Benefit Claims**

Benefit claims under 35 U.S.C. § 120 must include a specific reference to the earlier filed (nonprovisional) application for which a benefit is sought. A "specific reference" requires: (1) the identification of the prior (nonprovisional) application by **application number**; and (2) an indication of the **relationship** between the nonprovisional applications, except for the benefit claim to the prior application in a continued prosecution application (CPA). The relationship between any two nonprovisional applications will be an indication that the later-filed nonprovisional

Art Unit: 1644

application is either a continuation, divisional, or continuation-in-part of the prior-filed nonprovisional application. When there are benefit claims to multiple prior nonprovisional applications (e.g., a string of prior nonprovisional applications), the relationship must include an identification of **each** nonprovisional application as either a continuation, divisional, or continuation-in-part application of a specific prior nonprovisional application for which a benefit is claimed. The identification is needed in order to be able to verify if copendency exists throughout the entire chain of prior nonprovisional applications.

**35 U.S.C. § 119(e) Benefit Claims**

Benefit claims under 35 U.S.C. § 119(e) must include a specific reference to the earlier filed provisional application for which a benefit is sought. A specific reference in this situation, however, only requires identification of the prior provisional application by the application number. No relationship between the subject nonprovisional application and the prior provisional application should be specified. If the subject nonprovisional application was not filed within twelve months of the filing date of the provisional application, the subject application must also include a benefit claim under 35 U.S.C. § 120 to an intermediate prior nonprovisional application that was filed within twelve months of the filing date of the provisional application. Therefore, in addition to the identification of the provisional application, the proper benefit claim for this situation must also identify the intermediate prior nonprovisional application that is directly claiming the benefit of the provisional application, and indicate the relationship between the nonprovisional applications (e.g., an indication that the subject application is a continuation of the intermediate prior nonprovisional application).

***Information Disclosure Statement***

4. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered. Specifically a list of references is disclosed on pages 94-103.

***Oath/Declaration***

5. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Art Unit: 1644

Specifically, non-initialed and non-dated alterations have been made to the address of both inventors.

In addition priority to PCT/US97/20170 should be claimed under 35 U.S.C. 120.

***Specification***

6. The disclosure is objected to because of the following informalities: The use of the trademarks "SULFO-NHS-LC-BIOTIN", "MICROBCA" on page 72 have been noted in this application. It should be capitalized or accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. Each letter of the trademark must be capitalized. See MPEP 608.1(V) and Appendix 1. Appropriate corrections are required.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims encompass a method for detecting a cancer cell in a sample comprising identifying MICA or MICB expression in said sample. Said method encompasses MICA or MICB binding agents, wherein said binding agent is an antibody that can be labeled or can be bound by a second antibody, which in turn can be labeled. Said method also encompasses amplifying a MICA or MICB transcript.

The specification discloses on page 9 that the "inventors have shown that MICA is expressed in various cancer cell lines suggesting that cells may be screened for the overexpression of MICA and/or MICB, its presence indicating potential carcinogenesis". The specification further discloses that the "expression of MICA in tumor cells provides a marker for diagnostic screening methods for cancer in, for example, tumor or tissue biopsy samples" (page

Art Unit: 1644

10, lines 4-5), and that "MICA and/or MICB expression in tumor cells may be detected" (page 10, lines 5-6).

The specification discloses page 10 at lines 1-4 "an involvement of MICA with colon carcinoma" as well as with a variety of other tumors, however, it is not clear what said involvement means. The specification also discloses on page 76, lines 24-26 that "variable amounts of MICA were detected on endothelial tumor cell lines such as HT29 colon carcinoma and U373 astrocytoma cells, as indicated by antibody binding and flow cytometry and by immunoprecipitation of the surface labeled protein", however it is not clear what is encompassed by the phrase "variable amounts" and whether a negative result is encompassed by said phrase. Further it is not clear that the expression of MICA in two endothelial cell lines is indicative of the expression of MICB and/or MICA in actual endothelial cancers, or any endothelial cancers or in any cancers recited in claims 24-25, since the specification does not exemplify the identification of MICA or MICB expression in any sample containing cancer cells.

It is noted that the specification does not exemplify detecting a cancer cell in said sample comprising identifying expression of MICA or MICB in said sample. The art at the time the invention was made teaches that MICA and MICB are expressed almost exclusively in the gastrointestinal epithelium, as evidenced by Groh et al (PNAS 93:12445-12450)(IDS) see entire article, especially the Abstract, but does not indicate its expression as being associated with cancer cells. Given that the state of the art at the time the invention was made does not appear to teach the expression of MICA or MICB in association with cancer cells, and given the limited guidance in the specification regarding a method for detecting a cancer cell in a sample comprising identifying expression of MICA or MICB in said sample, it would require undue experimentation for one of skill to predict which if any types of cancer cells could be detected in a sample comprising identifying expression of MICA or MICB in said sample, without further guidance from the specification.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 872-9306 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Application/Control Number: 09/855,612

Page 6

Art Unit: 1644

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Group 1640,  
March 4, 2003

*Amy DeCloux*  
3-4-03